

## **REMARKS**

This is a Response to the Office Action mailed February 11, 2004. Claims 1-25 are pending in the application. Claims 1-19 have been rejected by the Examiner. As noted above, Applicants have amended Claim 1, 8 and 17-19, and added New Claims 20-25. The amendments are fully supported by the written description, for example at least on page 7 of the Specification. Also, New Claims 20-25 are fully supported by the written description. Also, no new matter has been introduced into the application.

### ***Claim Rejections – 35 USC § 103***

#### **A. Wink et al. in view of Hoek et al.—Claims 1, 3, 6-8, 14 and 15**

Claims 1, 3, 6-8, 14 and 15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wink et al. (WO 94/02845) in view of Hoek et al. (U.S. Patent Number 6,615,067). Wink et al. is directed to an electrode sensor that can be used to measure nitric oxide concentration in solution. See Abstract. Hoek et al. is directed to a guide wire for measuring physiological characteristics inside a body. See Abstract.

Applicants respectfully submit that the claimed invention is allowable over Wink et al. and Hoek et al. because these references, alone or in combination, fail to disclose all of the claimed limitations. Wink et al. clearly fail to disclose a basic part of the claimed invention—namely, that the electrode sensor is included in an elongated wire assembly. The Hoek et al. reference does not make up for this deficiency because the structure of the Hoek et al. device is fundamentally different than the claimed invention. It is the Examiner's position that Hoek et al. discloses an "assembly having a core section including a lumen (32), and an opening in the core section in fluid communication with the vessel," and that the "sensor (32) is positioned within the lumen so that the sensor is in fluid communication with the vessel." Sensor 32, however,

clearly **projects out** from the body of guide wire 210, and therefore is not positioned **within the lumen** of the core section so that the sensor is in **fluid communication with the vessel through the opening**. The spatial relationship of electrode 32 and the body of guidewire is most clearly shown in Figure 7 of Hoek et al. The difference between the Hoek et al. device and the claimed invention is neither subtle, nor trivial. Truly, one of ordinary skill in the art would recognize the Hoek et al. device to be both structurally and functionally different than the present invention. Electrode 32 of Hoek et al. extends out from the body of the guidewire so that it can receive an electric current directed through the body fluids by output signal electrode 17. See Col. 7, line 64 to Col. 8, line 4. One of ordinary skill in the art would not even think to place electrode 32 into the body of the guidewire because it would adversely affect the electrode's ability to receive the electric current from the output electrode.

In short, Wink et al. and Hoek et al. at least fail to disclose, "a sensor positioned within the lumen of the elongated member so that the sensor is in fluid communication with the vessel through the opening." Accordingly, Claims 1 and 8 are allowable. Claims 3, 6 and 7 depend from Claim 1; and Claims 14 and 15 depend from Claim 8. These dependent claims should be allowable over the references for at least the same reason.

**B. Soller in view of Saadat—Claims 1, 2, 4, 5, 7-9, 11, 13, 15 and 17-19**

Claims 1, 2, 4, 5-7, 11, 13, 15 and 17-19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Soller (U.S. Patent Number 5,582,170) in view of Saadat (US 2003/0013985). Soller is directed to a fiber optic sensor for measurement of in vivo nitric oxide concentrations in a subject. The sensor contains a nitric oxide-sensing compound in a polymer matrix attached to an optical fiber. See Abstract. Saadat is directed to a method of sensing the temperature profile of a hollow body organ. See Abstract.

Applicants respectfully submit that the claimed invention is allowable over Soller in view of Saadat because these references, alone or in combination, fail to disclose all of the claimed limitations. With respect to independent Claims 1, 8 and 19, the references at least fail to disclose, “a sensor positioned within the lumen of the elongated member so that the sensor is in fluid communication with the vessel.”

It appears that it is the Examiner’s position that the Saadat reference discloses that guidewire 20 includes an opening so that thermal sensor 25 is in fluid communication with the body vessel. Applicants respectfully disagree, and submit that the Examiner is misinterpreting the disclosure of Saadat. It is clear from the Figures of Saadat, and the disclosure overall, that Saadat never contemplates having an opening in guidewire 20 so that body fluids can enter the lumen of guidewire 20. For instance, Saadat specifically discloses that temperature sensor 25 is not in fluid communication with the blood in the vessel, but rather is in thermal communication through the wall of guidewire 20. In particular, Saadat states, “[w]ith guidewire 20 exposed and lying in helical contact with the wall 14 of blood vessel 12, **the temperature probe 23 is able to sense the localized temperature of the vessel wall 14 through the guidewire 20 at the region where the thermal sensor 25 is located.**” Page 2, paragraph 28 (emphasis added). As shown in Figures 2, 3, 4 and 6, in all instances, Saadat discloses that temperature sensor 25 must be in contact with the inner surface of the guidewire body, and therefore no opening is needed nor disclosed. As shown in the enclosed figure from Saadat (labeled as “Attachment A”), the guidewire does not have an opening, and in fact has a closed end. Because the Saadat guidewire device lacks an opening, it is clearly different than the claimed invention. There is no need to have an opening for Saadat since the measurement is thermal in nature.

With respect to Claim 19, Saadat also fails to disclose that the temperature sensor is bendable “away from a central longitudinal axis of a distal end of the elongated member.” The Examiner cites paragraph 24 as providing the disclosure that the sensor is bendable. **However, paragraph 24 only refers to the movement of the entire guidewire structure, not the movement of the sensor relative to the guidewire body.** There is nothing in paragraph 24, nor anything else in the disclosure, that suggests that the “sensor includes a sensor tip capable of bending away from a central longitudinal axis of a distal end of the elongated member.” Accordingly, Claim 19 is allowable over Soller in view of Saadat.

In light of the above remarks, Applicants respectfully submit the Examiner to reconsider the finding of obviousness, and allow Claims 1, 2, 4, 5-7, 11, 13, 15 and 17-19.

**C. Soller in view of Saadat and Cooke et al.—Claims 10, 12 and 16**

Claims 10, 12 and 16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Soller in view of Saadat and further in view of Cooke et al. (U.S. Patent Number 5,945,452). As noted above, Claim 8 is allowable over Soller in view of Saadat. The disclosure of Cooke et al. does not cure the deficiencies of these prior art references as related to Claim 8. Accordingly, Claim 8 is allowable over Soller in view of Saadat and further in view of Cooke et al. Claims 10, 12 and 16 depend directly or indirectly from Claim 8, and are allowable for at least the same reason.

**D. Saadat in view of Schock et al.—Claims 1, 2, 8, 9 and 17-19**

Claims 1, 2, 8, 9 and 17-19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Saadat in view of Schock et al. (US 2002/0072680). As noted above, Saadat does not disclose all of the limitations of the present invention. For instance, Saadat at least does not disclose, “a sensor positioned within the lumen of the elongated member so that the sensor is

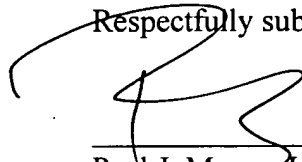
in fluid communication with the vessel.” The disclosure of Schock et al. does not cure the deficiencies of Saadat. In particular, Schock et al. specifically discloses that the fiber optic sensor would be protected from blood contact. See, e.g., page 3, paragraph 36 (“Diaphragm 80 may be made from silicone approximately 6 microns thick and is **protected from physical damage and blood contact** by protective pocket 82, which may contain a gel, fluid, gas, elastomer, or any other flexible protective material”) (emphasis added). Accordingly, independent Claims 1, 8 and 19 are allowable over Saadat in view of Schock et al. Dependent Claims 2, 9, 17 and 18 should be allowable for at least the same reason.

### CONCLUSION

Claims 1-25 are pending in this application. Examination and allowance of the claims are respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 954-0345.

Date: July 12, 2004  
Squire, Sanders & Dempsey L.L.P.  
One Maritime Plaza, Suite 300  
San Francisco, CA 94111  
Telephone (415) 954-0200  
Facsimile (415) 393-9887

Respectfully submitted,



---

Paul J. Meyer, Jr.  
Attorney for Applicants  
Reg. No. 47,791